IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

DNA GENOTEK INC., Plaintiff, v. SPECTRUM DNA; SPECTRUM SOLUTIONS L.L.C.; and SPECTRUM PACKAGING L.L.C., Defendants.	C.A. No. 15-cv-00661-SLR **JURY TRIAL DEMANDED**

PLAINTIFF DNA GENOTEK INC.'S OPENING BRIEF IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION

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Dated: August 24, 2015

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I. INTRODUCTION AND SUMMARY OF THE ARGUMENT

Plaintiff DNA Genotek Inc. ("DNAG") is a leading provider of products for biological sample collection, such as saliva collection devices for DNA testing. Defendants Spectrum DNA, Spectrum Solutions L.L.C., and Spectrum Packaging, L.L.C. (collectively, "Spectrum") have surreptitiously marketed a competing saliva collection device that infringes DNAG's U.S. Patent No. 8,221,381 ("the '381 patent") and competes with DNAG's top products. On or about July 31, 2015, Spectrum came out of hiding, revealing itself through a new website, www.spectrum-dna.com, and advertising its infringing product for sale to the general public. Spectrum's infringing conduct and its targeting of DNAG's current customers is causing and will continue to cause DNAG irreparable harm. DNAG, therefore, respectfully moves this Court to issue a preliminary injunction immediately prohibiting Spectrum's infringement.

II. STATEMENT OF THE NATURE AND STAGE OF THE PROCEEDINGS

This patent infringement suit stems from Spectrum's recent launch of a website offering infringing saliva collection devices to the public. DNAG suspects that Spectrum has been the secret supplier of infringing kits for Ancestry.com DNA LLC ("Ancestry"), a defendant in a separate suit by DNAG pending in this court. DNAG discovered on July 28, 2015, that Mr. Gregg Williams, owner of Defendant Spectrum Solutions, registered that same day a website with the domain name, www.spectrum-dna.com. The website was not yet operational. The next day, DNAG discovered a marketing company's website hosting what in the last couple of weeks has become Spectrum DNA's website offering infringing saliva collection devices for sale to the general public, as opposed to just Ancestry. DNAG reviewed online pictures of the infringing device and determined that Spectrum's device infringed the '381 patent. DNAG filed its complaint the next day and immediately sought to obtain samples of the Spectrum DNA devices.

After receiving samples through a third party and confirming the infringement, DNAG immediately began retaining expert witnesses and drafting this motion for an injunction. Spectrum has been served, but has not answered the complaint.

III. STATEMENT OF FACTS

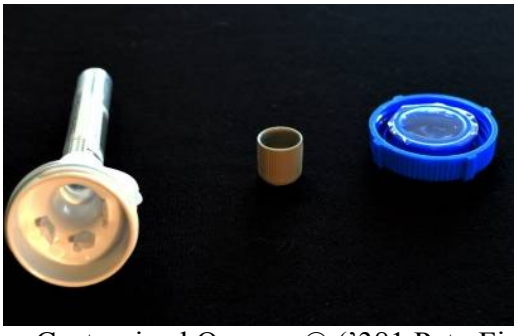
A. DNAG is a Leading Innovator of DNA Collection Technology.

DNAG makes high quality products for biological sample collection, including oral fluid sample collection and stabilization solutions for molecular applications. DNAG revolutionized the DNA collection market with products that provide substantial advantages over traditional methods of biological sample collection. DNAG's products are protected by a robust patent estate. Representative examples of DNAG patented products are depicted below. (*See* Declaration of Ian Curry ("Curry Decl.") ¶ 5).

Oragene●One® (OG-510) (multiple patents)

OraGene●RNA® ('381 Pat., Figs. 22-24)

Oragene●Discover ('381 Pat., Figs. 4-11)

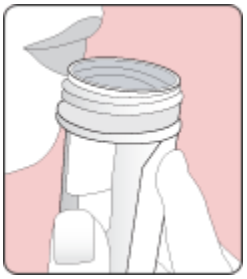


Customized Oragene® ('381 Pat., Figs. 12-21)

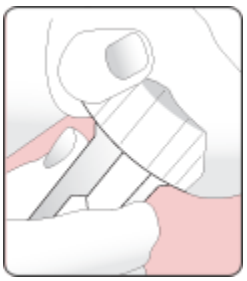
B. The ’381 Patent Encompasses Many Embodiments of DNAG’s Sample Collection Devices.

Each of the above four devices is an embodiment of a DNA (or other sample) collection device covered by the ’381 patent, which is entitled “Container System for Releasably Storing a Substance.” Very generally, the ’381 patent describes “two compartment” DNA collection containers. One compartment houses a “substance,” such as a DNA preservative. The other compartment stores a “sample,” such as a user’s saliva. When in use, the separately stored “substance” and “sample” are mixed together so the combined substance-sample (*e.g.*, saliva in a DNA preservative) can be shipped for further testing. Taking the OraGene●RNA product (Figures 22-24 of the ’381 patent), for example, the device has two main components and works in two steps. The components are (1) a collection tube with a “sample” (e.g., saliva) storage area and (2) a lid with a compartment for storing a “substance” (*e.g.*, a DNA or RNA preservative) before the sample is collected. To use the device, a user first fills the collection tube with saliva.






Second, the user places the red lid on the collection tube.


When the user screws on the lid, the "piercing members" (*e.g.*, teeth) at the top of the collection tube pierce the membrane in the lid. That releases the preservative from the lid into the sample collection tube, mixing the preservative and saliva. The preserved sample can then be tested. (Curry Decl. ¶ 5, Ex. A.)

While the OraGene●RNA device is a two-step device, other embodiments of the '381 patent have more steps. For example, the Oragene●One® (OG-510) device is a four-step device. The '381 patent has only apparatus claims. They are not limited to a particular number of steps.

C. Spectrum's Product Infringes At Least Claim 1 of the '381 Patent.

Claim 1 of the '381 patent is representative of the claims infringed by Spectrum.

1. A container system for releasably storing a substance, comprising:

> a) a vial comprising a first open end for receiving a sample, a second end comprising a sample storage chamber and a piercing member, wherein said piercing member comprises a side wall, a first cutting edge extending from a first pointed corner to a second corner that defines the intersection between said cutting edge and said side wall; and
>
> b) a lid configured to removably engage said vial, said lid comprising a reservoir for holding the substance, and a pierceable membrane sealing the substance within said reservoir,
>
> wherein, when said system is closed by removable engagement of said vial with said lid, said vial and said lid are movable to a piercing position in which the piercing member disrupts the pierceable membrane to allow fluid communication between said reservoir and said chamber, wherein the chamber is sealed against leakage to the outside of the container system in the piercing position.

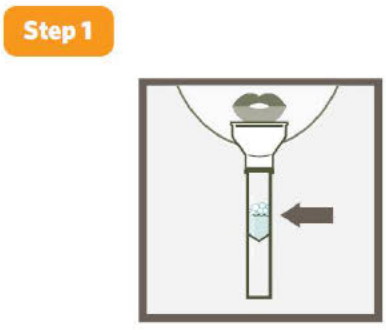
(Declaration of Juan C. Lasheras, Ph.D. ("Lasheras Decl."), Ex. B., Claim 1 (emphasis added).)

As set forth in more detail in the attached declaration of Dr. Juan C. Lasheras, Director of the Center for Medical Devices and Instrumentation at the University of California, San Diego, and a Fellow of the National Academy of Inventors, the Spectrum device meets every limitation

of claim 1 of the '381 patent, either literally or under the doctrine of equivalents. Dr. Lasheras obtained samples of the Spectrum device and concluded that every limitation is met. He then prepared a claim chart showing how the Spectrum device infringes on a limitation-by-limitation basis. Briefly, the Spectrum device, pictured below, has three components and works using a three-step method. The three components are: (1) a collection tube with a saliva storage area; (2) a lid with a compartment for storing a DNA preservative; and (3) a removable funnel.

(*See* Lasheras Decl. ¶ 9.)

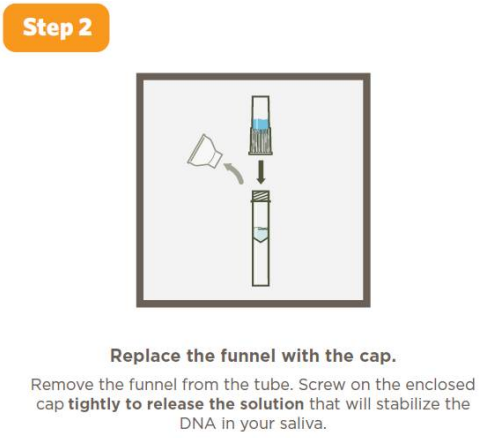
Spectrum's package insert describes how to use the Spectrum device. First, a user fills the collection tube by spitting saliva through the funnel and into the sample storage area.



Fill the tube with saliva to the black wavy line.

Fill the tube until your saliva (not including bubbles) is at or just above the wavy line. Do not overfill.

Second, the funnel is removed. Finally, the lid with the compartment for storing a DNA preservative is screwed on the tube. [1]



The device works when the piercing member, initially in the bottom of the lid, wedges into the collection tube and moves up to pierce the membrane in the lid, causing the stored preservative to mix with the sample. (Lasheras Decl. ¶ 28, Ex. E.)

Spectrum's product infringes at least claim 1 of the '381 patent. There can be no serious dispute that the Spectrum device includes the claimed "first open end for receiving a sample," "second end comprising a sample storage chamber," "piercing member," "lid," "reservoir," and

[1] DNAG calls removing the funnel from the collection tube and replacing it with the lid two distinct steps. Spectrum calls it a single step. The distinction is unimportant here, as the number of steps is not a claim limitation.

"pierceable membrane." Each element is present in the Spectrum device. (Lasheras Decl. ¶¶ 17-30, Ex. F.) The only difference between the Spectrum device and the commercial embodiments of the DNAG devices is that, when it arrives in a box, the "piercing member" of the Spectrum device is located in the lid, as opposed to the collection tube. Thus, Spectrum might argue that its product does not literally infringe because the "piercing member" is not part of the claimed "vial." But the claim only requires that the vial "compris[e]" a piercing member. The word "comprising" is an open-ended transitional phrase synonymous with the word "including." *See Manual of Patent Examination Procedure* § 2111.03 (2014); *see also Gillette Co. v. Energizer Holdings, Inc.*, 405 F.3d 1367, 1371-73 (Fed. Cir. 2005). When in use, the piercing member becomes wedged in the top of the collection tube, making a "vial" that comprises both a collection tube and a piercing member, as required by the claims.

(Lasheras Decl. ¶ 21.) Even if the "piercing member" limitation is not met literally, the accused piercing member in the Spectrum device, depicted below, is insubstantially different than the piercing members claimed by claim 1 of the '381 patent.

Specifically, Spectrum's piercing member performs the same function (rupturing the membrane), in the same way (by cutting the membrane), and achieves the same result (the substance and sample are mixed) as the "piercing member" in claim 1 of the '381 patent. (Lasheras Decl. ¶¶

22-23.) Accordingly, it infringes claim 1, at least under the doctrine of equivalents.

IV. ARGUMENT

A party seeking preliminary injunction relief must demonstrate: (1) a reasonable likelihood of success on the merits; (2) the prospect of irreparable harm in the absence of an injunction; (3) that this harm would exceed harm to the opposing party; and (4) the public interest favors such relief. *See, e.g., Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008); *Sciele Pharma Inc. v. Lupin Ltd*., 684 F.3d 1253, 1259 (Fed. Cir. 2012); *Abbott Labs. v. Sandoz, Inc*., 544 F.3d 1341, 1344 (Fed. Cir. 2008). The first two requirements – likelihood of success on the merits and probability of irreparable harm if relief is not granted – are the key requirements. *See Antares Pharma., Inc. v. Medac Pharma., Inc.*, 55 F. Supp. 3d 526, 529 (D. Del.) (citing *McKeesport Hosp. v. Accreditation Council for Graduate Med. Educ*., 24 F.3d 519, 523 (3d Cir. 1994), *aff'd*, 771 F.3d 1354 (Fed. Cir. 2014).

A. DNAG Will Likely Succeed on the Merits

At the preliminary injunction stage of a case, the movant "must demonstrate that . . . at least one of [the] allegedly infringed claims will . . . likely withstand the validity challenges presented by the accused infringer." *Abbott Labs. v. Andrx Pharms., Inc,* 452 F.3d 1331, 1335 (Fed. Cir. 2006) (citation omitted). Spectrum is represented by Ancestry's counsel in this case. DNAG and Ancestry have been in discussions since May, and neither Spectrum, nor Ancestry, has articulated any invalidity or unenforceability defense to DNAG. To the extent Spectrum plans to challenge the '381 patent, it will be entitled to a statutory presumption of validity. 35 U.S.C. § 282; *see also Applied Materials, Inc. v. Advanced Semiconductor Materials Am., Inc.*, 98 F.3d 1563, 1569 (Fed. Cir. 1996) ("When a patent has been examined and duly granted, judicial review must give due weight to the presumption of validity."). Spectrum has the burden

of proving by clear and convincing evidence that the patent is invalid. This presumption exists at every stage of the litigation. *Canon Computer Sys., Inc. v. Nu-Kote Int'l, Inc.*, 134 F.3d 1085, 1088 (Fed. Cir. 1998) (affirming grant of preliminary injunction). Based on this presumption, the very existence of the patent, standing alone, is sufficient to satisfy DNAG's burden as to validity in the context of a preliminary injunction motion. *Id.*

Second, Spectrum's product infringes the '381 patent. Like any infringement analysis, determining likelihood of success on infringement in the context of a preliminary injunction motion involves two steps: claim construction and a comparison of the claims to the accused products. *Pfizer, Inc. v. Teva Pharms. USA, Inc.*, 429 F.3d 1364, 1372-1373 (Fed. Cir. 2005). For purposes of a preliminary injunction, the Court need not interpret the claims conclusively and finally. *Sofamor Danek Group, Inc. v. DePuy-Motech, Inc.*, 74 F.3d 1216, 1221 (Fed. Cir. 1996). Rather, the Court need only determine "whether the accused device is likely to fall within the scope of the claims." *Id.* at 1220. "To establish literal infringement, all of the elements of the claim, as correctly construed, must be present in the accused system." *TechSearch, L.L.C. v. Intel Corp.,* 286 F.3d 1360, 1371 (Fed. Cir. 2002). A product that does not literally infringe may still infringe under the doctrine of equivalents if the differences between an element of the claimed invention and an element of the accused product are insubstantial. *See Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 40 (1997) (infringement exists when the accused device "contain[s] elements identical or equivalent to each claimed element of the patented invention"). The "function-way-result test" is one way to determine if any difference between the accused device and the claimed invention is, in fact, insubstantial. A patentee satisfies the function-way-result test by proving that the accused product performs substantially the same function in substantially the same way to achieve substantially the same result as the

claimed invention. *Graver Tank & Mfg. Co. v. Linde Air Prods. Co*., 339 U.S. 605, 608 (1950); *see also TIP Sys., LLC v. Phillips & Brooks/Gladwin, Inc.*, 529 F.3d 1364, 1376 (Fed. Cir. 2008) (citing *Graver Tank*).

Dr. Lasheras's declaration sets forth in detail his opinion that the Spectrum device infringes claim 1 of the '381 patent. Each limitation is literally present. For completeness, Dr. Lasheras alternatively addresses infringement of the "piercing member" limitation under the doctrine of equivalents. The function of the claimed "piercing member" is to rupture the membrane of the reservoir and release the reservoir fluid. In other words, its function is to cut open the "reservoir," which is storing the "substance." The Spectrum device's piercing member performs that same function. The way this is achieved is by pressing pointed corners and a cutting edge against the membrane, causing the membrane to tear and the "substance" (*e.g.*, preservative) to pour out through the cut membrane. The result in each is the same. The "substance" mixes with the "sample." There are no differences, let alone "substantial" differences, which are required to take the Spectrum device outside the scope of infringement under the doctrine of equivalents. A preliminary finding of infringement under the doctrine of equivalents is a sufficient basis to determine that DNAG is likely to succeed on the merits. *See Abbott Labs. v. Andrx Pharms., Inc.*, 473 F.3d 1196, 1213 (Fed. Cir. 2007) (affirming grant of preliminary injunction after finding infringement under doctrine of equivalents).

B. DNAG Will Be Irreparably Harmed if the Court Does Not Issue a Preliminary Injunction

A party seeking injunctive relief must establish that it is likely to suffer irreparable harm in the absence of preliminary relief. *Trebro Mfg. v. FireFly Equip., LLC*, 748 F.3d 1159, 1165 (Fed. Cir. 2014). In the patent context, a patentee seeking injunctive relief must also show a

causal nexus between the infringing feature and consumer demand for the accused product. *Apple Inc. v. Samsung Elecs. Co.*, 695 F.3d 1370, 1375 (Fed. Cir. 2012).

Harm is likely to be irreparable where, as here, the patentee and infringer are direct competitors, because the patentee is forced to compete against its own invention. *Trebro Mfg., Inc.*, 748 F.3d at 1171; *Douglas Dynamics, LLC v. Buyers Prods. Co.*, 717 F.3d 1336, 1345 (Fed. Cir. 2013); *Presidio Components, Inc. v. Am. Tech. Ceramics Corp.*, 702 F.3d 1351, 1363 (Fed. Cir. 2012); Curry Decl. ¶¶ 17-21 (noting that Spectrum's product is a direct competitor for the DNAG Saliva Collection Products). "Indeed, the principal value of a patent is the right to exclude arch competitors from making, selling and using an infringing product." *Butamax™ Advanced Biofuels LLC v. Gevo, Inc.*, 868 F. Supp. 2d 359, 374 (D. Del. 2012) (quoting *Fresenius Med. Care Holdings, Inc. v. Baxter Int'l, Inc.*, 2008 WL 928496, at *3 (N.D. Cal. Apr. 4, 2008)).

1. DNAG Will Suffer Irreparable Harm As a Result of Spectrum's Infringing Conduct

DNAG will suffer price erosion, loss of goodwill and damage to its reputation, and loss of business opportunities unless Spectrum is enjoined. The Federal Circuit has repeatedly recognized each of these market harms as irreparable. *See, e.g., Aria Diagnostics, Inc. v. Sequenom, Inc.*, 726 F.3d 1296, 1304 (Fed. Cir. 2013); *Celsis in Vitro, Inc. v. CellzDirect, Inc.*, 664 F.3d 922, 930 (Fed. Cir. 2012); *see also Opticians Assoc. of Am. v. Indep. Opticians of Am.,* 920 F.2d 187, 196 (3d Cir. 1990) ("Potential damage to reputation constitutes irreparable injury for the purposes of granting a preliminary injunction in a trademark case.").

a. Spectrum's Infringing Product Will Cause DNAG to Suffer Price Erosion

Erosion of market prices due to an infringer's conduct constitutes irreparable harm

justifying a preliminary injunction. In *Polymer Technologies, Inc. v. Bridwell*, 103 F.3d 970 (Fed. Cir. 1996), the Federal Circuit reversed the denial of a preliminary injunction and explained that the effects of price erosion cannot be remedied through money damages:

> Competitors change the marketplace. Years after infringement has begun, it may be impossible to restore a patentee's (or an exclusive licensee's) exclusive position by an award of damages and a permanent injunction. Customers may have established relationships with infringers. The market is rarely the same when a market of multiple sellers is suddenly converted to one with a single seller by legal fiat. *Requiring purchasers to pay higher prices after years of paying lower prices to infringers is not a reliable business option.*

103 F.3d at 975-76 (emphasis added); *see also Aria Diagnostics*, 726 F.3d at 1304 (price erosion is a recognized irreparable harm). As Dr. DeForest McDuff explains in his accompanying declaration, competition from an infringing product reduces the price the patent holder can charge, causing depressed prices. (McDuff Decl. ¶ 16.) Price erosion is particularly impactful where, as here, the competing products are economic substitutes. (*Id.* ¶¶ 17-22.)

DNAG is particularly susceptible to price erosion. DNAG invests significant amounts of money in research and development in order to maintain its position as the technology leader in the market. (Curry Decl. ¶¶ 4, 7-9.) It also invests in costly quality control measures, and is ISO certified for medical device quality management and compliant with FDA medical device quality system requirements. (*Id.* ¶¶ 8-9.) Because DNAG must sell its Saliva Collection Products at a price sufficient to recoup its research and development expenses while continuing to innovate, its products are the most expensive ones in the market. (*Id.* ¶ 9.) Due to its comparatively expensive product, DNAG is vulnerable to price-based competition that will result in degradation of pricing and profit margins. (McDuff Decl. ¶ 17 (referencing public financial disclosures).)

b. Spectrum's Infringing Product Will Damage DNAG's Relationship with Current and Potential Customers

Harm to a company's brand distinction and reputation in the market is sufficiently irreparable to warrant an injunction. *Douglas Dynamics, LLC*, 717 F.3d at 1344; *Celsis*, 664 F.3d at 930 (loss of goodwill and damage to reputation are grounds for finding irreparable harm). For example, where a cheaper product makes its place in the market "by infringing on the intellectual property of the [better product] and capitaliz[ing] on its similarity to the better product," then harm goes "beyond a simple counting of lost sales." *Douglas Dynamics*, 717 F.3d at 1344. Likewise, where an infringer attempts to take for itself the benefits of a patentee's innovations and market development efforts, the resulting harm to the patentee's goodwill and reputation is irreparable. *See 3M Unitek Corp. v. Ormco Co*., 96 F. Supp. 2d 1042, 1051 (C.D. Cal. 2000) ("If defendant is allowed to free ride on plaintiffs' innovation and technological achievements it will permanently injure plaintiffs' reputation and goodwill within the orthodontic community.")

If Spectrum is allowed to market its knock-off version of DNAG's patented product, DNAG will suffer irreparable harm to its brand distinction, its reputation as an innovator, and the customer goodwill that it has spent years developing. DNAG's business reputation is based on the success and performance of the Saliva Collection Products. (Curry Decl. ¶¶ 4-6.) Many of DNAG's customers actually know DNAG as "the Oragene company"—the tradename for the Saliva Collection Products—rather than its actual business name. (*Id.* ¶ 5.)

The key feature distinguishing the revolutionary Saliva Collection Products from DNAG's competitors is the two-compartment container system covered by the '381 patent. (Curry Decl. ¶ 7.) This two-compartment container system reduces user error and allows DNAG

to market a system that "just works." (*Id.* ¶¶ 7, 10.) Spectrum is the only competitor of which DNAG is aware that uses the DNAG's patented container design. Spectrum's newly-launched website touts the benefits of its infringing design, claiming "reduce[d] customer collection errors," and "significantly reduce[d] costs associated with sample failures and recollection." (McDuff Decl. ¶ 19.) Spectrum's marketing of this infringing product, using the same product claims as DNAG, will force DNAG to "lose some of its distinctiveness and market lure." *Douglas Dynamics*, 717 F.3d at 1344; (McDuff Decl. ¶ 23 (DNAG's loss of the ability to differentiate its product risks price erosion).) Moreover, Spectrum offers custom packaging, which further enhances the irreparable harm to DNAG's reputation by creating the perception that DNAG's patented technology is available from a number of different sources. (McDuff Decl. ¶¶ 28-30.) Such damage to DNAG's reputation as an innovator cannot be fully compensated by payment of damages. *Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 2014 U.S. Dist. LEXIS 88488, at *8 (D. Del. June 30, 2014).

Additionally, the market for biological sample collection kits is highly referential, meaning that buyers monitor and follow the purchasing decisions of other buyers. (Curry Decl. ¶¶ 11-15.) For example, academic customers, like university researchers, read peer-reviewed journals to see what tools other researchers are using in their experiments. (*Id.* ¶ 13.) These same researchers will also face pressure from within their institutions as to why they are not using lower-cost alternatives mentioned in journal articles. (*Id.* ¶¶ 11-15.) Similarly, commercial customers, like for-profit genetic testing companies, buy their competitors' test kits to see if there are better value products available. (*Id.*) As a consequence of this market behavior, DNAG faces a domino effect of market losses. (Curry Decl. ¶¶ 14-15; McDuff Decl. ¶ 31.) The potential buyers of the Saliva Collection Products will notice when someone buys the

Spectrum device instead and, given the nature of the market, this act causes its own irreparable harm to DNAG's goodwill, customer base, and market reputation. (Curry Decl. ¶¶ 11-15.) These losses in customer base and reputation will be unpredictable and difficult to measure, as customers frequently order on an as-needed basis and DNAG does not learn of lost customer accounts until it discovers the customer using a competing product. (*Id.* ¶¶ 14-15.)

Finally, DNAG's business is based on irregular sales and bulk sales. (Curry Decl. ¶¶ 11-15.) DNAG's Saliva Collection products are therefore especially sensitive to irreparable harm from lost customers. *See Celsis*, 664 F.3d at 930 (finding irreparable harm where "market was particularly sensitive because customers buy in bulk and at irregular times, such that the loss of a single sale in this market may be more harmful than for products purchased daily"); McDuff Decl. ¶ 30 (unpredictable ordering schedules will increase likelihood of lost customers).

c. Spectrum's Infringing Product Will Harm DNAG's Ability to Do Business

Courts have recognized that a patentee is irreparably harmed by infringing conduct that jeopardizes its business operations. *Bio-Techn. Gen. Corp. v. Genentech, Inc*., 80 F.3d 1553, 1565-566 (Fed. Cir. 1996). For example, irreparable harm exists where a patentee would have to scale back research and development activities if an infringer were allowed to enter the market. *Id.* at 1566. Irreparable harm also exists where denying a preliminary injunction could lead to layoffs. *Sanofi-Synthelabo v. Apotex Inc.*, 488 F. Supp. 2d 317, 342 (S.D.N.Y. 2006), *aff'd* 470 F.3d 1368, 1382-83 (Fed. Cir. 2006) (granting preliminary injunction based on "independent evidence of irreparable harm, namely, [that patentee] . . . will be forced to lay off personnel and discontinue research devoted to developing other medical uses for Plavix").

Here, DNAG's Saliva Collection Products are the single most important piece of its

business. (Curry Decl. ¶¶ 5-6.) About 80% of DNAG's overall revenue comes from the Saliva Collection Products. (*Id.* ¶ 6.) Any lost sales of Saliva Collection Products therefore directly impact DNAG's bottom line and its ability to pursue future projects, which is an important component of DNAG's business. (*See* McDuff Decl. ¶¶ 33-34 (discussing public disclosures regarding need for continuous investment).) A significant loss of sales of Saliva collection products will jeopardize DNAG's entire business, and will result in layoffs of key employees. (Curry Decl. ¶ 6.) Given that Spectrum has already been supplying a major DNAG customer, Ancestry.com, and a potential Japanese customer, as well as having solicited at least one other DNAG customer, *see id.* ¶¶ 18-21, there is an objectively high likelihood that Spectrum will take a significant portion of DNAG's sales if allowed to continue its infringing conduct. Therefore, it is likely that, absent an injunction, DNAG will be irreparably harmed by reduced research and development opportunities and layoffs.

2. Spectrum's Ability to Pay Money Damages is Uncertain

It is well-settled that damages are an inadequate remedy and a plaintiff faces irreparable harm if the defendant's ability to satisfy a money judgment is uncertain. *See, e.g., Robert Bosch LLC v. Pylon Mfg. Corp*., 659 F.3d 1142, 1154-56 (Fed. Cir. 2011). In the present case, the available evidence shows a high likelihood that Spectrum could not satisfy a judgment against it for lost profits or reasonable royalties. The Spectrum entities are small and secretive. Detailed data about their business is unascertainable from public records. (Declaration of Brian M. Kramer ("Kramer Decl.") ¶¶ 2-6.) The information available, however, suggests that Spectrum Solutions, LLC (the parent entity) has approximately five employees. The only available Dun & Bradstreet estimate of Spectrum's annual revenue is a $200,000 estimate for Spectrum Packaging, although Spectrum's sales to DNAG's former customer, Ancestry, have presumably

been in the millions. (*Id.* ¶ 6; McDuff Decl. ¶ 29; Curry Decl. ¶21.) Spectrum's sales to Ancestry have already led to millions of dollars in lost sales damages. Spectrum may be unable to satisfy a judgment for even these past damages, much less damages for any future sales of the infringing product. Accordingly, in addition to the irreparable harms identified in the sections above, in the absence of an injunction DNAG is likely to suffer money damages for which Spectrum is unable to provide compensation. This is a separate irreparable harm warranting injunctive relief. *Robert Bosch LLC*, 659 F.3d at 1154-56.

3. DNAG's Harm Is Directly Attributable to Spectrum's Infringement

Federal Circuit precedent requires a showing of some causal nexus between the alleged infringement and the alleged harm. *See Apple Inc. v. Samsung Elecs. Co.*, 735 F.3d 1352, 1359-60 (Fed. Cir. 2013) ("Sales lost to an infringing product cannot irreparably harm a patentee if consumers buy that product for reasons other than the patented features.").

In determining whether a causal nexus exists between the Spectrum device and harm to DNAG, "[t]he relevant question is not whether there is some causal relationship between the asserted injury and the infringing conduct, but to what extent the harm resulting from selling the accused product can be ascribed to the infringement." *Apple*, 695 F.3d at 1375. For relatively simple products, like the one at issue here, the causal nexus analysis is "more easily satisfied." *Apple Inc.*, 735 F.3d at 1362 (analysis more easily satisfied for windshield wiper blades or orthopedic screws than complex smartphones).

As discussed in the likelihood of success section above, the '381 patent covers the entire Spectrum container system. The innovative and patented design of the DNAG Saliva Collection Products is a key selling feature for DNAG, which allows its sales staff to show customers how

the Saliva Collection Products "just work" compared to the competition. (Curry Decl. ¶¶ 7, 10.) The patented nature of this technology is even expressly referenced by DNAG in customer pitches. (*Id.* ¶ 10.) Spectrum is now using this same technology as a basis for its own advertising, including claims of "reduce[d] customer collection errors," and "significantly reduce[d] costs associated with sample failures and recollection." (McDuff Decl. ¶ 19.) Thus, the causal relationship between harm and infringement is direct and clear. (McDuff Decl. ¶¶ 35-37 (causal connection between economic harm and asserted technology is evidenced by Spectrum's marketing and instruction materials).)

4. Harm to DNAG is Already Occurring; More Harm is Imminent

Although DNAG did not know of Spectrum's identity until recently, Spectrum has already taken DNAG's former customer, Ancestry. Ancestry had been a DNAG customer for two years and accounted for millions of dollars in sales. (Curry Decl. ¶ 21.)

Additionally, DNAG recently discovered that Spectrum's infringing product—disguised with custom branding—has been marketed to at least one Japanese market customer that DNAG had been pursuing for over a year. (Curry Decl. ¶ 19.) While the customer is located outside the United States, Spectrum's behavior amounts to an act of infringement because Spectrum manufactures the device in the United States, offers it for sale from the United States, and presumably exports the device from its Utah-based manufacturing facility. DNAG also recently learned that at least one of its repeat customers had been solicited with the infringing product. (*Id.* ¶ 20.)

Spectrum's plan to increase its competitive footprint against DNAG is evident. Spectrum recently came out of the shadows and began officially advertising its product through its new website, spectrum-dna.com. (Kramer Decl. ¶ 4.) Spectrum's website contains high-resolution

photographs advertising its infringing products and inviting potential customers to email, call, or submit a price quote form. (*Id.* ¶ 3, Ex. E.) Spectrum launched its website months after DNAG sued Spectrum's largest customer, making clear that it intends to ramp up its manufacture and sale of infringing products in the face of infringement allegations, causing DNAG serious harm.

C. The Balance of Hardships Weighs in Favor of Issuing an Injunction

Without an injunction, DNAG would be forced "to compete against its own patented invention, with the resultant [irreparable] harms described above, [which] places a substantial hardship on [DNAG]." *Robert Bosch LLC*, 659 F.3d at 1156. Spectrum's lower-cost, infringing product could disrupt the market such that DNAG will suffer serious and irreparable harm to its business. (*See* Section IV.B.) Issuing an injunction prohibiting Spectrum from marketing or selling its product to any customers other than Ancestry, however, primarily requires only that Spectrum take down a website it launched only days ago. Any harm that Spectrum might suffer in lost opportunities with other customers is speculative and de minimus in relation to the irreparable harm that DNAG will endure if an injunction does not issue.

Any hardship that Spectrum might endure if enjoined, furthermore, would be "the result of its own calculated risk in selling a product with knowledge of [DNAG's] patent." *Celsis*, 664 F.3d at 931. A party cannot be heard to complain of an injunction that may harm its business after it "elect[ed] to build a business on a product found to infringe . . . ." *Windsurfing Int'l, Inc. v. AMF, Inc.*, 782 F.2d 995, 1003 n.12 (Fed. Cir. 1986). Spectrum knows about DNAG and its patented saliva collection devices. Both Ancestry and Spectrum are represented by the same counsel. Moreover, Spectrum's website brazenly uses a picture of DNAG's patented device, which includes a patent number and reference to other pending patents, among pictures of its own device as evidence of Spectrum's packaging capabilities. (*See* Curry Decl. ¶ 21, Ex. B at 5.)

Spectrum should not complain that an injunction is a hardship because it purposely evaded detection for two years, colluding with Ancestry to make infringing products using product labels that suggested that Ancestry, not Spectrum, was the actual manufacturer. Spectrum did not launch its website offering its infringing device to the public until two months after DNAG sued Ancestry.

D. The Public Interest Weighs in Favor of Issuing an Injunction

Courts "have long acknowledged the importance of the patent system in encouraging innovation." *Sanofi*, 470 F.3d at 1383. DNAG has invested substantial resources in developing its patent portfolio, and such an investment "must be encouraged and protected by the exclusionary rights conveyed in valid patents." *Celsis*, 664 F.3d at 931. In exchange for the public's promise to protect its exclusionary rights, DNAG has developed breakthrough products in the DNA collection space that are currently utilized by the public in academic settings, commercial industries, and clinical environments. But DNAG's incentive to create and deliver innovation to the public, indeed the incentive of any inventor to share creativity with the public, "would be adversely affected by taking market benefits away from the patentee and giving them to the accused infringer . . . ." *Id.* at 932.

V. CONCLUSION

DNAG requests that the Court grant its Motion for a Preliminary Injunction.

Respectfully submitted,

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Dated: August 24, 2015